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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,235	11/06/2001	Seth Lederman		5392

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,235	LEDERMAN ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/07/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to applicant's amendment received April 7, 2006.

Claims 9-21 are cancelled. New claims 23-24 are added. PLEASE NOTE: the claims have been misnumbered, i.e. claim 21, 23, 24. Pursuant to Rule 126, the claims have been renumbered. Claims 1-8 and 22-23 are currently pending.

The previous rejection of claims 1-8 under 35 USC 112, second paragraph, set forth in paragraph 1 of the office action mailed Oct. 19, 2005, is withdrawn in view of applicant's amendment and the remarks contained therein.

The claims and specification have been subject to further review. Issues discussed during the review are addressed below.

New Ground(s) of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the

claimed invention. The claims are drawn to a pharmaceutical composition comprising an effective amount of (R,R'),(R,S')-amphetaminil sulfate for the treatment or prevention of "a disorder benefiting from or requiring a central nervous system stimulant," wherein the composition is substantially free of (S,R),(S,S')-amphetaminil. The claimed composition fails to meet the requirement for an adequate written description of the claimed invention as required by 35 USC, 112, paragraph 1. There is insufficient descriptive support for the generic limitation "a disorder benefiting from or requiring a central nervous system stimulant." The claimed composition requires treatment of an unspecified disease. Other than the diseases described in the specification (pages 3-4 and pages 7-8), no evidence indicates that other treatable diseases within the generic limitation were known to Applicant. In the absence of some understanding of the other diseases to be treated one of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed composition.

Claim 23 limits the composition of claim 22 by reciting the specific disorders to be treated with (R,R'),(R,S')-amphetaminil sulfate. Specifically, claim 23 recites pain as one of the disorders. However, there is insufficient descriptive support for a pharmaceutical composition containing an effective amount of (R,R'),(R,S')-amphetaminil sulfate for the treatment of pain. Applicant's originally filed disclosure does not direct the skilled artisan to a pharmaceutical composition, where the specifically claimed compound, i.e. (R,R'),(R,S')-amphetaminil sulfate, by itself is used for treating pain. In fact, the specification describes that the claimed composition is to be combined with an opiate for the treatment of pain because the (R,R'),(R,S')-amphetaminil sulfate potentiates the activity of an opiate used in the treatment of pain (see page 4, lines 1-2). Thus, because this limitation renders claim 23 broader than what was originally

disclosed, one of ordinary skill in the art would not have concluded that Applicant was in possession of the method as claimed.

Claim Rejection(s)—35 USC 101

The pending claims have been reviewed in light of the the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, first paragraph, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-8 and 22-23 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

It is noted that Example 4 studies the effect of (R,R'),(R,S')-amphetaminil sulfate on locomotor activity and the induction of stereotyped behavior in normal rats. At the beginning of the experiment, rats were placed in standard perspex behavior boxes with a visible grid on the floor to allow determination of locomotor activity. Following drug administration the rats were returned to the behavior cages and locomotor activity was assessed for a further 5 hours or until baseline was achieved, whichever was sooner. Locomotor activity was assessed by videoing the rats throughout the experiment, and counting the number of times a rat crossed a grid line over a period of 5 minutes every 10 minutes. Additionally, throughout the experiment animals were scored for stereotyped behaviors for 15 seconds every 10 minutes by a trained observer using the

scoring methods described in Table 2 (page 29). The data demonstrates that (R,R'),(R,S')-amphetaminil sulfate increased locomotor activity at a dose of 10mg/kg and increased stereotypy at 10mg/kg. Moreover, (R,R'),(R,S')-amphetaminil sulfate exhibited a higher ratio at both the time of peak effect and total effect versus that of the racemic amphetaminil. Thus, the claimed compound may be less likely to elicit or exacerbate movement disorders in patients. Since tics are prevalent in about 12% of ADHD patients, the claimed compound may be better suited for treatment than the racemate (page 33 of the specification).

The examiner does not find an adequate nexus between the evidence described in Example 4 and the asserted utility in claims 22 and 23. Absent factual evidence, the observed stereotypy and locomotor behavior observed in rats is not deemed to reasonably support a link to the claimed disorders requiring a CNS stimulant (claim 22) such as those in claim 23. The need for further research to define any specific or substantial utility clearly indicates that the instant claims are directed to subject matter for which there is no currently available utility thus supporting this rejection. Note, because the claimed utility is not supported by a specific and/or substantial asserted utility for the reasons set forth above, credibility has not been assessed.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claims 1-8, 22-23 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Conclusion

Claims 1-8, 22-23 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Ardin Marschel**, can be reached on **571-272-0718**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
June 19, 2006

Cybille Delacroix-Muirheid
Patent Examiner Group 1600